NORTH DAKOTA
DEPARTMENT of HEALTH

Radioactive Material Licensing Guide: Use of Rubidium-82 Generators For PET/CT

1. Specify the radionuclide, chemical/physical form, activity per generator, maximum possession limit, manufacturer/distributor of the generator, model name/number, and description of use.

2. Specify the PET/CT equipment that will be used.

3. Provide drawings showing where the rubidium-82 generator will be stored and used, where injection and imaging will be conducted, and where any radioactive waste will be stored. Show which rooms are upstairs, downstairs, and adjacent to these rooms, and identify the uses of those rooms.

4. Through calculations, demonstrate that the public dose limits of 2 millirem in any one hour and 100 millirem in a year will not be exceeded in the upstairs, downstairs, and adjacent rooms identified in #3 above. Commit to using area monitors or conducting surveys to verify that public dose limits are not exceeded.

5. Commit to restricting and posting the areas where the generator will be used and stored as radiation areas.

6. Describe the methods that will be used to prevent unauthorized access to or theft of the generator. Also, how will unauthorized access be prevented when the generator is delivered to your facility, and when it is shipped for disposal.

7. Commit to following the infusion system user's guide, the package insert for the generator, any additional manufacturer's operating manuals and instructions, and the manufacturer's recommended emergency procedures for the generator and infusion system, including:

    a. Patient administration may be performed only after successful completion of daily calibration, Sr-82 and Sr-85 breakthrough procedures, and first wash elution disposal, using settings specified by the manufacturer for these procedures. In the event of a power-failure or the system is inadvertently shut down, calibration should be reconfirmed.

    b. Each generator eluate at the end of elution must not contain more than 0.02 microcurie of Sr-82 and not more than 0.2 microcurie of Sr-85 per millicurie of rubidium chloride Rb-82 injection, and not more than 1 microgram of tin per milliliter of eluate.

c. Any servicing and maintenance on the generator and infusion system should be performed by the manufacturer.

d. Annual preventive maintenance service should be performed by the manufacturer.

e. The waste bottle should be emptied every morning prior to system use or at the end of system usage.

8. Commit to having all users (physician authorized users, nuclear medicine technologists, CT operators, nursing staff, etc.) trained by the manufacturer or an individual trained by the manufacturer. For training not provided by the manufacturer, commit to including all topics covered in the manufacturer's training program. Commit to maintaining records of all training for inspection.

9. Identify the authorized physician user(s) to be granted privileges, and provide evidence of training and experience or prior license specific PET authorizations.

10. Explain generator exchange procedures. If the manufacturer will not be exchanging the generators, state who will be exchanging the generators and commit to providing them with the manufacturer-recommended training for personnel who exchange generators.

11. Commit to using radiation survey meters and a dose calibrator that are appropriate for use with positron-emitting radioactive materials.

12. Explain how time, distance, and shielding will be used to minimize radiation exposures to physician authorized users, nuclear medicine technologists, CT operators, nursing staff, etc. Describe additional shielding and handling equipment for controlling the high-energy positron and gamma emissions from shipments, patients, and waste.

Dated: November 2004